

SEP 13 2006

K062319

## 510(k) Summary – Calibrator for Automated Systems (C.f.a.s)

**Introduction** Roche Diagnostics Corporation hereby submits this Special 510(k): Device Modification to provide notification of modifications to our Calibrator for Automated Systems (C.f.a.s.). This calibrator was originally cleared for use as K990460 and modified via K033501.

Modifications to the calibrator include:

- Modification to reagent composition: addition of pyridoxal phosphate
- Change of stability claim after reconstitution
- Modifications to value assignment procedure: including use of internal laboratory
- Changes to traceability for select analytes

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**Submitter name, address, contact** Roche Diagnostics  
9115 Hague Rd  
Indianapolis IN 46250  
(317) 521-3723

Contact person: Corina Harper

Date prepared: May 12, 2006

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**Device Name** Proprietary name: Calibrator for Automated Systems (C.f.a.s.)

Common name: Calibrator for Automated Systems (C.f.a.s.)

Classification name: Calibrator, Multi-analyte mixture

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**Device Description** Calibrator for Automated Systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche chemistry analyzers as specified in the enclosed value sheet.

Calibrator for Automated Systems (C.f.a.s.) is a lyophilized calibrator based on human serum.

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**Intended use** Calibrator for Automated Systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche chemistry analyzers as specified in the enclosed value sheet.

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**Predicate Device** We claim substantial equivalence to the Calibrator for Automated Systems (C.f.a.s.) cleared as K033501.

**Substantial equivalency – Similarities/Differences** The table below indicates the similarities and differences between the modified Calibrator for Automated Systems (C.f.a.s.) and its predicate device (Calibrator for Automated Systems (C.f.a.s.), K033501).

| Feature                                 | Predicate device: C.f.a.s.<br>(K033501)   | Modified device: C.f.a.s.   |
|---|---|---|
| <b>General</b>                          |   |   |
| Intended Use/<br>Indications for<br>Use | Calibrator for Automated Systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the lot specific value sheet. | Same  |
| <b>Reagent information</b>              |   |   |
| Reagent<br>composition                  | Lyophilized human serum with chemical additives and material of biological origin   | Same<br>Pyridoxal-phosphate addition  |
| Stability - shelf<br>life and on-board  | 2-8 °C until expiration date<br><br>Reconstituted:<br>8 hours at 15 to 25° C<br>2 days at 2 to 8° C<br>8 hours at 15 to 25° C<br>2 weeks (frozen once) at (-15) to (-25)° C                 | Same<br><br>Reconstituted:<br>8 hours at 15 to 25° C<br>2 days at 2 to 8° C<br>8 hours at 15 to 25° C<br>4 weeks (frozen once) at (-15) to (-25)° C |

|                  |   |  |
|------------------|---|--|
| Traceability     | Traceability through Master Lot (ML) to standards or reference methods.   | Traceability through standards or reference methods analyzed at all set point validation runs.<br><br>Traceability changed for the following analytes:<br>Direct Bilirubin<br>Calcium<br>Creatinine, Jaffe/RB/Compensated Iron<br>Magnesium, Xyldyl Blue /Chlorophosphonazo<br>UIBC<br>Uric Acid |
| Value Assignment | Values to new lots are assigned by running them as samples after calibrating the system with the Master Lot of C.f.a.s. | Values to new lots are assigned by running them as samples after calibrating the system with previously assigned C.f.a.s lot. Values are verified by using reference material, Master lot C.f.a.s. and previously assigned lots of C.f.a.s.  |

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|                                      |   |
|--------------------------------------|---|
| <b>Proposed Labeling</b>             | Proposed labeling sufficient to describe the device, its intended use, and the directions for use can be found in Section V. We believe the proposed version of the device labeling presented contains all of the technical information required per 21 CFR 809.10.     |
| <b>Validation and Design Control</b> | Development activities were conducted under appropriate design control procedures and the overall product specifications were met. The Declaration of Conformity with Design Controls and Results of Risk Analysis are provided in Section 5.1. Analytical Performance. |
| <b>Confidentiality</b>               | Roche Diagnostics Corporation requests that the FDA not disclose the nature or existence of this submission until the substantial equivalence decision has been reached.  |

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**Closing**

Modification of the Calibrator for Automated Systems (C.f.a.s.) does not affect the intended use or indications for use of the device as described in the labeling, nor does it alter the fundamental scientific technology of the device. Therefore, we trust the information provided in this Special 510(k) will support a decision of substantial equivalence of the Calibrator for Automated Systems (C.f.a.s.) to the predicate.

If you have any questions or require further information, please do not hesitate to contact this office.

- Phone: (317) 521-3831
- FAX: (317) 521-2324
- email: corina.harper@roche.com

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## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Corina Harper  
Roche Diagnostics Corporation  
9115 Hague Road  
Indianapolis, IN 46250-0457

SEP 13 2006

Re: k062319  
Trade/Device Name: Calibrator for Automated System C.f.s.a.  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIX  
Dated: August 8, 2006  
Received: August 9, 2006

Dear Ms. Harper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

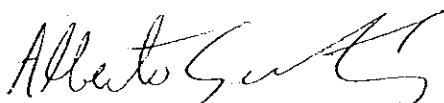
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Alberto Gutierrez, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K062319

Calibrator for automated systems: C.f.a.s.

### Indications For Use:

Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Prescription Use XXX

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Carol C Benson  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

K062319